ALTANA

Altana Inc. 60 Baylis Road, Melville, N.Y. 11747 631-454-7677

May 8, 2002

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
12420 Parklawn Dr. Room 1-23
Rockville, MD 20857

VIA FEDERAL EXPRESS

Dear Food and Drug Administration:

Citizen Petition

The undersigned submits this petition under 21 CFR §10.25 to request that the Commissioner of Food and Drugs amend the publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (Orange Book) for Fluocinonide Emulsified Base. Altana requests that Lidex-E® NDA 16-908-003 also be designated as the Reference Listed Drug for this product.

A. Action requested

The 22nd edition of the Orange Book designates both Lidex® and Lidex-E®, approved under NDA 16-908-002 and 16-908-003, respectively, as AB. Altana Inc. requests that Lidex-E® be designated as AB1 as the two drug products have been demonstrated to be bio-inequivalent.

B. Statement of grounds

Altana Inc. conducted a one-period, randomized, vasoconstrictor assay to compare the effects of two topical fluocinonide 0.05% creams (Lidex® and Lidex-E®). For the purpose of this study, Lidex-E® was considered the test product and Lidex® the Reference. Results obtained from this study yielded a test-to-reference ratio of 75.1 with a 90% confidence interval of 67.2 - 83.1%. This data does not meet the current limits of 80 - 120% for determining the bioequivalence of two topical corticosteroids.
In accordance with 21 CFR §10.20(a) and (c), four copies of the bioequivalence study and data diskette have been provided as **Attachment I**.

C. Environmental impact

Altana Inc. claims a categorical exclusion under 21 CFR §25.30 (h). In accordance with the provisions established in 21 CFR §25.23 and §25.24, the action that is the subject of this petition is excluded from the requirement to prepare an Environmental Assessment because the actions meet specific requirements that are intended to ensure that they will not cause significant environmental effects.

02P-0219

CP 1

D. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

All regulatory correspondence related to this Citizen Petition should be addressed to the following individual:

Ms. Audrey Bialeski
Manager, Regulatory Affairs
Altana, Inc.
60 Baylis Road
Melville, NY 11747
Telephone: (631) 454-7677, extension 3007
Facsimile: (631) 756-5114

Sincerely,
ALTANA INC.

Audrey Bialeski for/

Robert J. Anderson, Esq.
Senior Director, Scientific Affairs
60 Baylis Road
Melville, NY 11747
Telephone: (631) 454-7677, extension 2085
Facsimile: (631) 756-5114

RJA:jfa

ALTANA

Altana Inc. 60 Baylis Road, Melville, N.Y. 11747 631-454-7677

May 9, 2002

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane Room 1061
Rockville, MD 20852
Tel: 301-827-6869
Fax: 301-827-6870

VIA FACSIMILE

02 MAY -9 P1:19

Amendment
Citizen Petition

Dear Food and Drug Administration:

Further to the discussion on May 9, 2002 between FDA representatives and Altana personnel, Altana Inc. agrees that information contained in the submitted Citizen Petition can be included as part of the Public Docket. Please consider this correspondence as Altana's release for the confidential protocol included as part of the clinical study report.

If you have any questions or require additional information, please contact Ms. Audrey Bialeski at (631) 454-7677 extension 3007. FAX communications can be made to (631) 756-5114.

Sincerely,
ALTANA INC.

Robert J. Anderson, Esq.
Senior Director, Scientific Affairs

RJA:jfa

TELEFAX DATED: May 9, 2002

ALTANA

Altana Inc. 60 Baylis Road, Melville, NY 11747 631-454-7677 Fax: 631-756-5114

BYK GULDEN PHARMA GROUP

TO: Mr. Lyle Jaffe FAX NO: 301-827-6870

FROM: Mr. Robert J. Anderson, Esq.

OF PAGES (including this page): 2

Amendment
Citizen Petition

Dear Mr. Jaffe:

Reference is made to the conference call on Thursday, May 9, 2002, between FDA representatives and Altana personnel. As discussed, enclosed please find a Facsimile Amendment to the Altana Inc. Citizen Petition file dated May 8, 2002.

If you have any questions or require additional information, please contact Ms. Audrey Bialeski at (631) 454-7677 extension 3007. FAX communications can be made to (631) 756-5114.

Sincerely,
ALTANA INC.

for/
Audrey Bialeski

Robert J. Anderson, Esq.
Senior Director, Scientific Affairs

RJA:jfa

NOVUM
PHARMACEUTICAL RESEARCH SERVICES

A ONE PERIOD, RANDOMIZED, VASOCONSTRICTOR ASSAY STUDY TO COMPARE THE RELATIVE VASOCONSTRICTIVE EFFECTS OF TWO TOPICAL FLUOCINONIDE 0.05% CREAMS

STUDY NO. 10228207

DRUG:	**Fluocinonide, 0.05%**
PROTOCOL NO:	**10228207, Revision 1 (02/04/02)**
DESIGN:	**One-Period, Randomized, Vasoconstrictor Study**
TEST:	**Lidex-E® (fluocinonide) Cream, 0.05% Manufactured for MEDICIS, The Dermatology Company® by Patheon, Inc. Lot No. RAD028, Expiration date 02/03**
REFERENCE:	**Lidex® (fluocinonide) Cream, 0.05% Manufactured for MEDICIS, The Dermatology Company® by Patheon, Inc. Lot No. RAB040, Expiration date 02/04**
SPONSOR:	**Altana, Inc. Melville, NY**
PREPARED BY:	**Novum Pharmaceutical Research Services Pittsburgh, PA**
VOLUME:	**1 of 2**

NOVUM
PHARMACEUTICAL RESEARCH SERVICES

A ONE PERIOD, RANDOMIZED, VASOCONSTRICTOR ASSAY STUDY TO COMPARE THE RELATIVE VASOCONSTRICTIVE EFFECTS OF TWO TOPICAL FLUOCINONIDE 0.05% CREAMS

STUDY NO. 10228207

We authorize release of the final study report for this study which was performed in accordance with Protocol No. 10228207, Revision 1 (02/04/02).

Christopher H. Hendy, Ph.D.
President and CEO
Novum Pharmaceutical Research Services

3/21/02
Date

Valerie Balavage
Biostatistician
Novum Pharmaceutical Research Services

3/26/02
Date

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PHARMACEUTICAL RESEARCH SERVICES

QUALITY ASSURANCE STATEMENT

Sponsor:	Altana, Inc.
Drugs:	Lidex® E (fluocinonide) Cream 0.05% and Lidex® (fluocinonide) Cream 0.05%
Study Title:	A One Period, Randomized, Vasoconstrictor Assay Study To Compare the Relative Vasoconstrictive Effects of Two Topical Fluocinonide 0.05% Creams
Study Number:	10228207
Protocol Number:	10228207 (Revision 1)

CLINICAL OPERATIONS:
The following clinical operations were observed during study conduct:

Group 1: Dosing and Removal Procedures

REPORT:
The following text, tables, schedules and statistical data were reviewed for accurate representation within this report:

CLINICAL SUMMARY
Summary (Section 1)
Table C1: Subject Characteristics
Table C2: Schedule of Treatments and Actual Application and Removal Times
Table C3: Summary of Adverse Events
Activity Schedule
Meals and Menu Schedule

STATISTICAL ANALYSES
Verification of Treatment
Verification of Baseline Adjusted Readings
Verification of Corrected Baseline-Adjusted Readings
Verification of AUC calculations (ChromaMeter)

STATEMENT:
To the best of my knowledge, this report accurately represents the clinical conduct observed and data supplied for Quality Assurance review.

Joseph S. Henretty **Date:** 03/26/02

Joseph S. Henretty
Quality Assurance Specialist
Novum Pharmaceutical Research Services

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PHARMACEUTICAL RESEARCH SERVICES

CERTIFICATION OF GENERIC DRUG ENFORCEMENT ACT

Sponsor:	Altana, Inc.
Drug:	Lidex® E (fluocinonide) Cream 0.05% and Lidex® (fluocinonide) Cream 0.05%
Study Title:	A One Period, Randomized, Vasoconstrictor Assay Study To Compare the Relative Vasoconstrictive Effects of Two Topical Fluocinonide 0.05% Creams
Study Number:	10228207
Protocol Number:	10228207 (Revision 1)

In Compliance with the requirements of the Generic Drug Enforcement Act of 1992, Novum Pharmaceutical Research Services (Novum) hereby certifies to Altana, Inc. that Novum did not and will not use in any manner the services of any person debarred under subsection (a) or (b) of Section 306 of the Generic Drug Enforcement Act of 1992 (21 U.S.C. S335a) (the "Act"). Novum and affiliated persons of Novum responsible for the development or submission of any application for the approval of a drug product have not had or been involved in any convictions as described in subsections (a) and (b) of Section 306 of the Act. This certification is made solely for the benefit of Altana, Inc. and may not be used by any other person or entity. Novum also certifies that we employ all applicable Good Clinical Practices standards.

Marie R. Mayer
Director, Quality Assurance
Novum Pharmaceutical Research Services

03/26/02
Date

NOVUM
PHARMACEUTICAL RESEARCH SERVICES

CERTIFICATION OF FINANCIAL DISCLOSURE

Sponsor:	Altana, Inc.
Drugs:	Lidex® E (fluocinonide) Cream 0.05% and Lidex® (fluocinonide) Cream 0.05%
Study Title:	A One Period, Randomized, Vasoconstrictor Assay Study To Compare the Relative Vasoconstrictive Effects of Two Topical Fluocinonide 0.05% Creams
Study Number:	10228207
Protocol Number:	10228207 (Revision 1)

In compliance with the requirements of 21 CFR Part 54, Financial Disclosure by Clinical Investigators, Novum Pharmaceutical Research Services (Novum) hereby certifies to Altana, Inc. that none of the clinical investigators listed on the FDA 1572 for this study, nor their spouse or dependent children have:

- Received any compensation that was dependent on the outcome of the study, nor will they receive any additional payments such as royalty payments based on product sales.
- Have any equity interest such as ownership, stock options, or publicly traded stock in Altana, Inc. whose total value exceeds $50,000.
- Has any proprietary interests such as a patent, trademark, or licensing agreements in the product tested.
- Has received any other payment or equivalent from Altana, Inc., such as, on-going grant funding, consultant or honoraria payments, or clinical or laboratory equipment whose total value exceeds $25,000.

This certification covers the duration of the study and a period of twelve months from the date of the final report. This certification is made solely for the benefit of Altana, Inc., and is applicable only to the study defined above. It may not be used by any other person or entity nor for any other study conducted by Novum.

Marie D Boyer for

Christopher H. Hendy, Ph.D.
President and CEO
Novum Pharmaceutical Research Services

03/26/02
Date

FLUOCINONIDE STUDY NO. 10228207

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